



Attorney's Docket No. 047446/273072

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Appl. No.: | 10/762,078 | Confirmation No: | 4620 |
| Applicant(s): | Klass P. Hardeman | Group Art Unit: | 1623 |
| Filed: | January 21, 2004 | Examiner: | Lawrence E. Crane |
| Title: | ALKYL-LINKED NUCLEOTIDE COMPOSITIONS | | |

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RULE 37 C.F.R. §1.132 DECLARATION
of Dr. Steven E. Hall**

I, Dr. Steven E. Hall, do hereby declare as follows:

1. I am skilled in the art of the field of the invention described and claimed in the patent application referenced above. I received a Ph.D. in organic chemistry from the Massachusetts Institute of Technology and am currently Senior Vice President Research and Development at Serenex, Inc., the assignee of the subject patent application. I formerly was Vice President and Director of Sphinx Laboratories, Lilly Research Laboratories. I also have held senior management positions in medicinal chemistry at Bristol-Myers Squibb. A copy of my curriculum vitae is attached to this declaration.

2. I have read and understood the Office Action in the above-referenced patent application dated September 27, 2006. I also have read and understand the specification and currently pending claims of the subject application.

3. The Office Action states, in part, that the specification allegedly does not reasonably provide enablement to the method of testing encompassed by claim 31. See Office Action, at pages 2-3. For the reasons described below, I respectfully disagree.

4. Serenex, Inc., the assignee of the subject patent application, based on the teachings and disclosure of the subject patent application, currently uses embodiments of the nucleotide affinity medium disclosed and claimed in the patent application to screen for target compounds, for example, in drug discovery applications.

5. By way of example, as described in more detail herein below and as illustrated by the data presented in **Appendix A**, which is attached hereto, several known chemical compounds were screened against the purine-binding proteome of cultured human Jurkat cells using a D3 resin, which corresponds to a nucleotide affinity medium disclosed in Example 45 of the subject application.

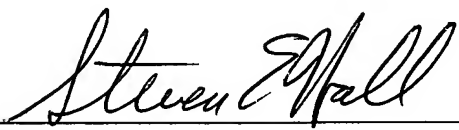
6. In this example, cultured human Jurkat cells were grown to density (2×10^9 cells/liter), harvested, pelleted by centrifugation and flash frozen in liquid nitrogen. The frozen cell pellet was thawed, homogenized in buffer, and sonicated to lyse the cells. The cell debris was removed by centrifugation and the resulting supernatant was mixed with D3 resin on ice with shaking. The resin was then collected in a gravity feed column, washed to remove non-specific binding, divided into smaller columns and eluted with the compounds identified in Scheme A1 of Appendix A. The compound/protein elutions were resolved by SDS-PAGE and visualized by silver staining.

7. As shown in Figure A1 of Appendix A, the SDS-PAGE gel shows several protein targets eluted with each compound. 5% DMSO is shown as a negative control. The primary targets for these compounds are listed in Table A1 and highlighted with the corresponding

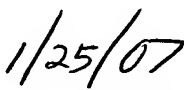
arrows on the gel image. The additional targets identified in the assay are also listed in Table A1.

8. For the above reasons, based on my education and scientific experience, I believe that the specification of the subject application enables one of ordinary skill in the art to use the presently claimed nucleotide affinity media to screen a test compound as set forth in the present claims.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

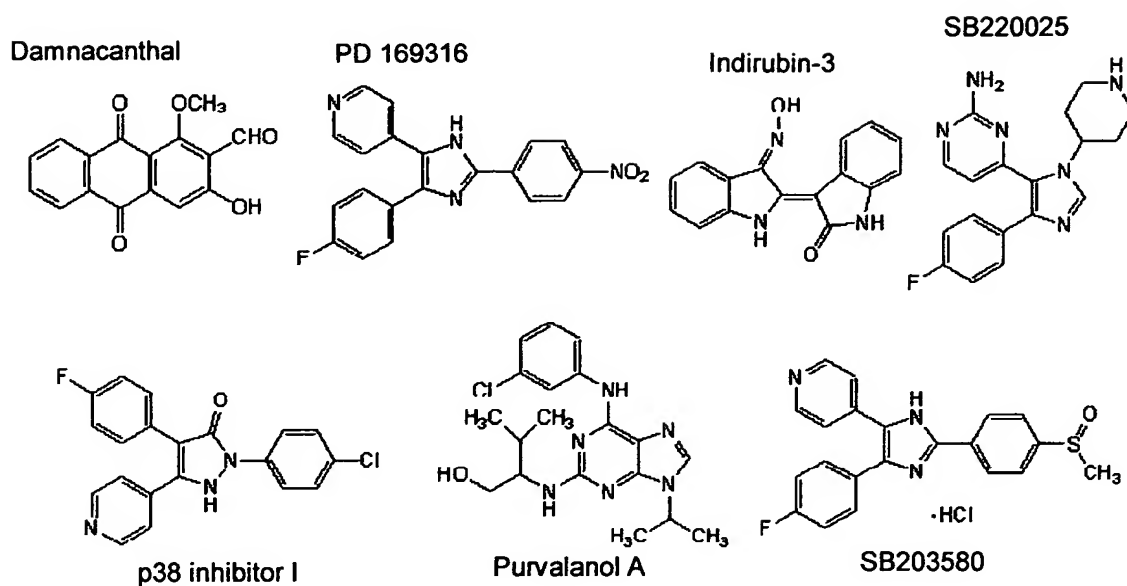


Dr. Steven E. Hall
Senior Vice President Research and Development
Serenex, Inc.
Durham, North Carolina



Date

APPENDIX A



Scheme A1. Representative known chemical compounds screened against the purine-binding proteome of cultured human Jurkat cells using a D3 resin.

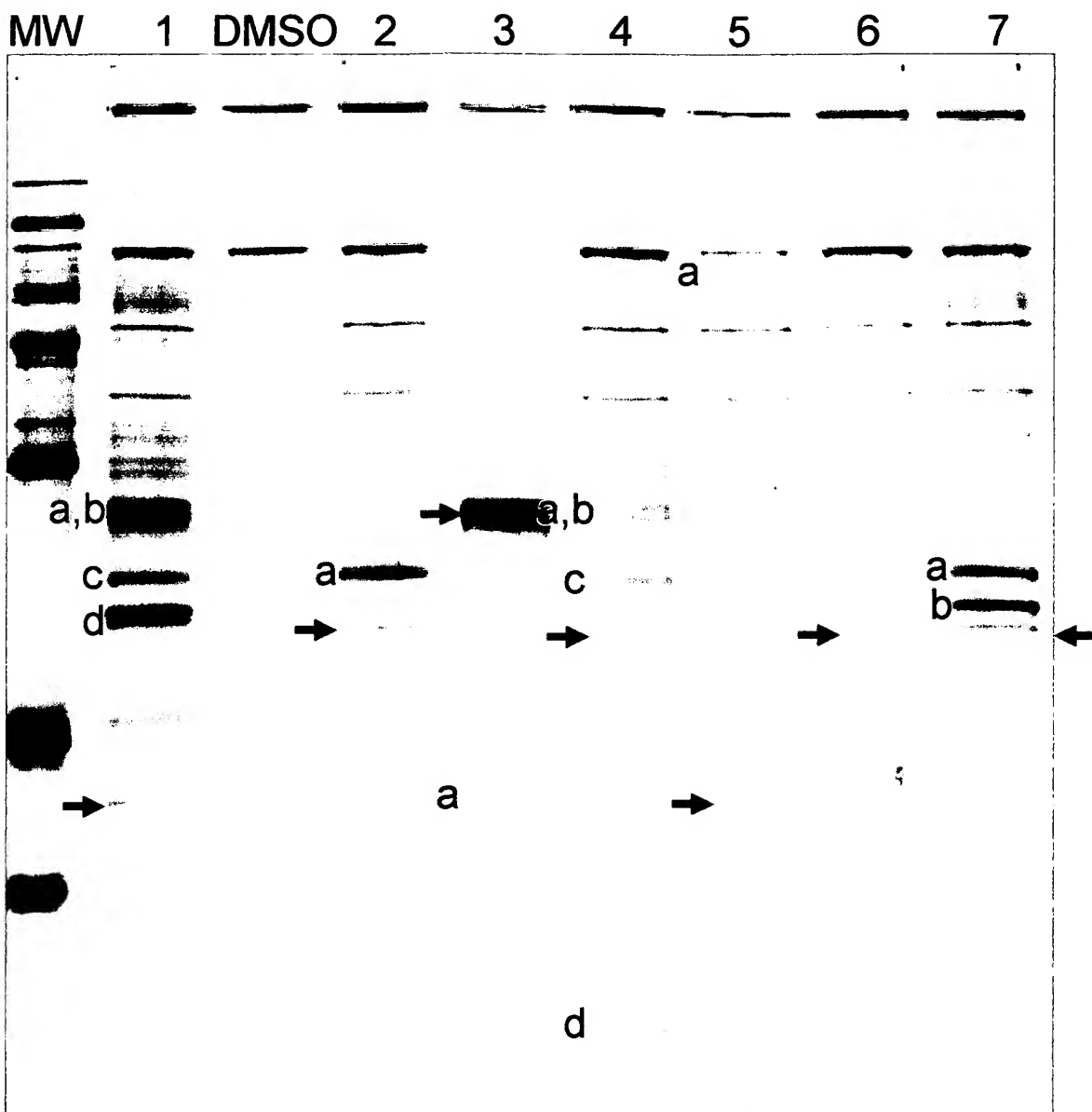


Figure A1. Representative SDS-PAGE gel showing several protein targets eluted with each compound shown in Scheme A1.

| Table A1. Targets Identified in Assay Using D3 Resin. | | |
|---|------------------|---------------------------------------|
| Compound | Expected Targets | Additional Targets |
| 1. Purvalanol A | Cdk1/Cdk2 | a. Yes b. Lck c. CSK d. MK01 |
| 2. p38 Inhibitor I | P38 MAPK | a. CSK |
| 3. Damnacanthal | Lck | a. Cdk1/Cdk2 |
| 4. SB 203580 | P38 MAPK | a. Yes b. Lck c. CSK d. DHFR |
| 5. Indirubin-3-monoxime | Cdk1/Cdk2 | a. P90 Rsk |
| 6. PD 169316 | P38 MAPK | |
| 7. SB 220025 | P38 MAPK | a. CSK b. MK01 |

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CIP

Manufactured in the United States of America

composite family

Compton

family. 4. *Composite*. *Archit.* Of, relating to, or being in the Composite order. — *n.* 1. A structure or an entity made up of distinct components. See *Syns* at *mixture*. 2. A complex material in which two or more distinct, structurally complementary substances combine to produce structural or functional properties not present in any individual component. 3. *Bot.* A composite plant. [Fr. < OFr. < Lat. *compositus*, p.p. of *componere*, to put together. See *COMPONENT*.] — *com·pos·ite·ly* *adv.* — *com·pos·ite·ness* *n.*

composite plant *n.* The largest family of flowering plants, the Compositae (Asteraceae), characterized by many small flowers arranged in a head looking like a single flower and subtended by an involucre of bracts.

composite number *n.* *Math.* An integer exactly divisible by at least one number other than itself or 1.

Composite order *n.* *Archit.* A Roman capital formed by superimposing ionic volutes on a Corinthian capital.

com·po·si·tion (kôm'pô-zish'ən) *n.* 1. a. The combining of distinct parts or elements to form a whole. b. The manner in which such parts are combined or related. c. General makeup: the changing composition of the electorate. d. The result or product of composing; a mixture or compound. 2. Arrangement of artistic parts so as to form a unified whole. 3. a. The art or act of composing a musical or literary work. b. A work of music, literature, or art, or its structure or organization. 4. A short essay, esp. one written as an academic exercise. 5. *Law.* A settlement whereby the creditors of a debtor about to enter bankruptcy agree to the discharge of their respective claims on receipt of a lesser amount than that actually owed. 6. *Ling.* The formation of compounds from separate words. 7. *Print.* Typesetting. [ME *composicioun* < OFr. *composition* < Lat. *compositio*, *compositiō* < *compositus*, p.p. of *componere*, to put together. See *COMPONENT*.] — *com·po·si·tion·al* *adj.* — *com·po·si·tion·al·ly* *adv.*

com·pos·i·tive (kâm-pôz'iv) *adj.* Synthetic; compounded. **com·pos·i·tor** (kâm-pôz'it-ər) *n.* *Print.* One that sets written material into type; a typesetter. [ME *compositur*, one who composes, settler of disputes < AN *compositour* < Lat., writer, compiler < *componere*, *composit-*, to put together. See *COMPONENT*.] — *com·pos·i·to·ri·al* (tôr'ē-əl, tôr'ē-) *adj.*

compos men·tis (mên'tis) *adj.* Of sound mind; sane. [Lat.: *compos*, having mastery of + *mentis*, genitive of *mens*, mind.]

com·post (kôm'pôst) *n.* 1. A mixture of decaying organic matter used to fertilize soil. 2. A composition; a mixture. — *tr.v.* *-post·ed*, *-post·ing*, *-posts*. 1. To fertilize with a mixture of decaying organic matter. 2. To convert (vegetable matter) to compost. [ME *composte* < OFr., mixture, compost < Lat. *compositum*, mixture < neut. p.p. of *componere*, to put together. See *COMPONENT*.]

com·po·sure (kâm-pô'zhər) *n.* A calm or tranquil state of mind; self-possession. [< *COMPOSE*.]

com·pote (kôm'pôt) *n.* 1. Fruit stewed or cooked in syrup. 2. A long-stemmed dish used for holding fruit, nuts, or candy. [Fr. < OFr. *composte*, mixture < Lat. *composita*, fem. p.p. of *componere*, to put together. See *COMPONENT*.]

com·pound (kôm'pound', kôm-, kôm'pound') *v.* *-pound·ed*, *-pound·ing*, *-pounds*. — *tr.* 1. To combine so as to form a whole; mix. 2. To produce or create by combining two or more ingredients or parts. 3. To settle (a debt, for example) by agreeing on an amount less than the claim; adjust. 4. To compute (interest) on the principal and accrued interest. 5. To add to; increase. — *intr.* 1. To form a compound. 2. To come to terms; agree. — *adj.* (kôm'pound', kôm'pound', kôm-). 1. Consisting of two or more substances, ingredients, elements, or parts. 2. *Bot.* Composed of more than one part. — *n.* (kôm'pound'). 1. A combination of two or more elements or parts. See *Syns* at *mixture*. 2. *Ling.* A word that consists either of two or more elements that are independent words, such as *loudspeaker*, or of specially modified combining forms of words, such as Greek *philosophia*, from *philos*, "loving," and *sophia*, "wisdom." 3. *Chem.* A substance consisting of atoms or ions of two or more different elements in definite proportions that cannot be separated by physical means. 4. *Bot.* a. A leaf whose blade is divided into two or more distinct leaflets. b. A pistil composed of two or more united carpels. [Alteration of ME *compounen* < OFr. *componre*, *compondre*, to put together < Lat. *componere*. See *COMPONENT*.] — *com·pound·a·ble* *adj.* — *com·pound·er* *n.*

com·pound (kôm'pound') *n.* 1. A building or buildings set off and enclosed by a barrier. 2. An enclosed area used for prisoners of war. [Alteration of Malay *kampung*, village.]

com·pound·com·plex sentence (kôm'pound-kôm'pléks) *n.* A sentence consisting of at least two coordinate independent clauses and one or more dependent clauses.

compound eye *n.* The eye of most insects and some crustaceans, which is composed of many light-sensitive elements, each forming a portion of an image.

compound fraction *n.* *Math.* See *complex fraction*.

compound fracture *n.* A fracture in which broken bone fragments lacerate soft tissue and protrude through an open wound in the skin.

compound interest *n.* Interest computed on the accumulated

unpaid interest as well as on the original principal.

compound lens *n.* See *lens* 2.

compound microscope *n.* A microscope consisting of an objective and an eyepiece at opposite ends of an adjustable tube.

compound number *n.* *Math.* A quantity that is expressed in terms of two or more different units, such as 10 pounds 6 ounces or 3 feet 4 inches.

compound sentence *n.* A sentence of two or more coordinate independent clauses, often joined by a conjunction or conjunctions.

com·pra·dor also **com·pra·dore** (kôm'pra-dôr') *n.* 1. A person between; an intermediary. 2. A native-born agent in China and certain other Asian countries formerly employed by foreign business to help with commercial transactions. [Fr. < LLat. *comparator*, buyer < Lat. *comparare*, to buy or compare, to get; see *per-* 1*.]

com·pre·hend (kôm'pri-hënd') *tr.v.* *-hend·ed*, *-hend·ing*, *-hends*. 1. To take in the meaning, nature, or importance of; grasp. See *Syns* at *apprehend*. 2. To take in as a part; include. [ME *comprehenden* < Lat. *comprehendere*; *com-*, *com-*, to take, to grasp; see *ghend-* 1*.] — *com·pre·hend·er* (kôm'pri-hënd-ər) *n.* — *com·pre·hend·ing·ly* *adv.*

com·pre·hen·si·ble (kôm'pri-hên'si-bəl) *adj.* 1. Readily comprehended or understood; intelligible. — *com·pre·hen·sibil·i·ty*, *com·pre·hen·si·ble·ness* *n.* — *com·pre·hen·sibly* *adv.*

com·pre·hen·sion (kôm'pri-hên'shən) *n.* 1. a. The act or fact of grasping the meaning, nature, or importance of; understanding. b. The knowledge that is acquired in this way. 2. Capacity to include. 3. *Logic.* The sum of meanings and corresponding implications inherent in a term. [ME *comprehensioun* < Lat. *comprehensio*, *comprehensio* < *comprehensum*, p.p. of *comprehendere*, to comprehend, to take in.]

com·pre·hen·sive (kôm'pri-hên'siv) *adj.* 1. So large in scope or content as to include much: a comprehensive history. 2. Marked by or showing extensive understanding: comprehensive. — *com·pre·hen·sive·ly* *adv.* — *com·pre·hen·sive·ness* *n.*

com·press (kâm'pres') *tr.v.* *-pressed*, *-press·ing*, *-press·es*. 1. To press together. 2. To make more compact by or as if by pressing. — *n.* (kôm'pres'). 1. *Medic.* A soft pad applied with pressure to a body part to control hemorrhage or to relieve heat, cold, moisture, or medication. 2. A machine for compressing material. [ME *compressen* < OFr. *comprece* < LLat. *compressare*, freq. of Lat. *comprimere* < *com-*, *com-*, to press; to press; see *per-* 4*.]

com·pressed (kâm'pres') *adj.* 1. Pressed together or into less volume or space. 2. *Biol.* Flattened, esp. laterally, or otherwise, as certain leafstalks or the bodies of many fishes.

compressed air *n.* Air under greater than atmospheric pressure, esp. when used to power a mechanical device or provide a portable supply of oxygen.

com·press·i·ble (kâm'pres'ə-bəl) *adj.* That can be compressed. — *com·press·i·bil·i·ty*, *com·press·i·ble·ness* *n.*

com·pres·sion (kâm'pres'hən) *n.* 1. a. The act or process of compressing. b. The state of being compressed. 2. a. The process by which the working substance in a heat engine is compressed. b. The engine cycle during which this process occurs.

compression wave *n.* A wave propagated by means of the compression of a fluid, as a sound wave.

com·pres·sive (kâm'pres'iv) *adj.* Serving to or able to compress. — *com·pres·sive·ly* *adv.*

com·pres·sor (kâm'pres'ər) *n.* One that compresses; esp. a machine used to compress gases.

com·prise (kâm'priz') *tr.v.* *-prised*, *-pris·ing*, *-pris·es*. 1. To consist of; be composed of. 2. To include; contain. 3. *Usage Problem.* To compose; constitute. [ME *comprisen* < OFr. *compris*, p.p. of *comprendre*, to include < Lat. *comprehendere*. See *COMPREHEND*.] — *com·pris·a·ble* *adj.*

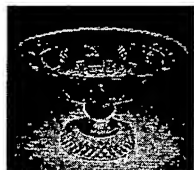
Usage Note: The whole comprises the parts; the parts compose the whole. In strict usage: *The Union comprises 50 states. Fifty states compose the Union.* While *comprise* is increasingly used in place of *compose*, in an earlier survey a majority of the Usage Panel found this use of *comprise* unacceptable. See Usage Note at *include*.

com·pro·mise (kôm'pra-miz') *n.* 1. a. A settlement of differences in which each side makes concessions. b. The result of such a settlement. 2. Something that combines qualities or elements of different things. 3. A concession to something detrimental or pejorative: a moral compromise. — *v.* *-mis·ed*, *-mis·es*. — *tr.* 1. To settle, by concessions: 2. To expose or make liable to danger, suspicion, or discredit. 3. *Obsolete.* To pledge mutually. — *intr.* To make a compromise. [ME *compromis* < OFr. < Lat. *compromissum*, mutual promise < neut. p.p. of *compromittere*, to promise mutually: *com-*, *com-*, + *promittere*, to promise; see *promis-* 1*.] — *com·pro·mis·er* *n.*

compt. *abbr.* Comptantment.

Com·ton (kôm'tən) *n.* A city of S CA, a suburb between Los Angeles and Long Beach. Pop. 90,454.

Compton, Arthur Holly. 1892–1962. Amer. physicist who shared a 1927 Nobel Prize.



compote
Mid 19th-century American
pressed glass compote made
by the Boston and Sandwich
Glass Company



compound eye
Magnified compound eye of
a green lacewing

com·troi·ler (kâm-trô'lar) *n.*

com·pul·sion (kâm-pûl'shən) *n.*

1. The state of being compelled.

2. The act, regardless of the rationality, of acts performed in response to a compulsion.

3. *Psychol.* Caused or caused by a sense of guilt. 2. A sense of doubt aroused by wrongdoing.

4. *Compun.* *com·punc·tion* (kâm-pûngk'shən) *n.*

1. To determine by mathematic.

2. To determine by the use of a termin.

3. *Comput.* *com·pu·ta·tion* (kôm'pyoo-tā'shən) *n.*

1. To determine by mathematic.

2. To determine by the use of a termin.

3. *Comput.* *com·pu·ta·tion* (kôm'pyoo-tā'shən) *n.*

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Fourteenth Edition

Revised by
Richard J. Lewis, Sr.



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complement. In immunochemistry, any of a number of blood proteins that act in conjunction with antibodies to cause disintegration of invading cells. They are an essential component of immune serum.

complex compound. See coordination compound.

complexing agent. See ligand; chelate; ethylenediaminetetraacetic acid.

complex ion. An ion that has a molecular structure consisting of a central atom bonded to other atoms by coordinate covalent bonds.
See coordination compound.

component. One of the minimum sets of substances required to generate the composition of all phases of a system in the absence of chemical reaction of any substances in a mixture.
See constituent.

composite. A mixture or mechanical combination on a macroscale of two or more materials that are solid in the finished state, are mutually insoluble, and differ in chemical nature. The major types are (1) Laminates of paper, fabric, or wood (veneer) and a thermosetting material (resin, rubber, or adhesive); examples are tire carcasses, plywood, and electrical insulating structures. (2) Reinforced plastics, principally of glass fiber and a thermosetting resin; other types of fibers such as boron, aluminum silicate, and silicon carbide may be used. See whiskers. (3) Cermets, which are mixtures of ceramic and metal powders, heat treated and compressed. (4) Fabrics, e.g., woven combinations of wool or cotton and a synthetic fiber. (5) Filled composites in which a bonding material, i.e., linseed oil, resin, or asphalt, is loaded with a filler in the form of flakes or small particles; examples are linoleum, glass flake-plastic mixtures for battery cases, and asphalt-gravel road-surfacing mixtures.

composting. Aerobic bacterial decomposition of solid organic wastes, both agricultural and urban, including sewage sludge. As much as 500 tons a day can be handled in the larger installations, the waste degrading quickly without external heating. Decomposition is accelerated by adding ammonium bicarbonate. The product can be used as a soil conditioner and for landfill. The waste is piled and turned frequently to provide aeration and to maintain a high temperature in the pile to destroy pathogenic organisms. The volume of composted waste is from 20 to 60% of original volume.

compound. (1) A substance composed of atoms or ions of two or more elements in chemical combination. The constituents are united by bonds or valence forces. A compound is a homogeneous entity where the elements have definite proportions by

weight and are represented by a chemical formula. A compound has characteristic properties quite different from those of its constituent elements. It is decomposed by energy in the form of a chemical reaction, heat, or electric current. Example: water is a liquid formed by chemical combination of two gases; it can be separated into hydrogen and oxygen by an electric current (electrolysis); in certain reactions it is split into its constituent ions (H, OH) (hydrolysis); it is not chemically changed by heat or cold.

See mixture; homogeneous; chemical reaction. (2) Loosely, a product formula (often proprietary) of various types, e.g., pharmaceuticals (a vegetable compound), rubber (a fast-curing compound), etc. (3) Having two sets of lenses (compound microscope).

compound 1080. Use may be restricted.
See sodium fluoroacetate.

compreg. A hardwood impregnated with a phenolformaldehyde resin under heat and pressure.

compressed gas. Any material or mixture that, when enclosed in a container, has an absolute pressure exceeding 40 psi at 21.1°C or, regardless of the pressure at 21.1°C, has an absolute pressure greater than 104 psi(a) at 54.4°C, or any flammable material having a vapor pressure greater than 40 psi abs at 37.7°C (vapor pressure determined by Reid method (ASTM)). Compressed gases include liquefied petroleum gases and oxygen, nitrogen, anhydrous ammonia, acetylene, nitrous oxide, and fluorocarbon gases. Some of these are shipped in tonnage volume. For details on properties, containers, and shipping regulations, see the entries for specific gases.

compression molding. Formation of a rubber or plastic article to a desired shape, by either placing the raw mixture in a specially designed cavity or bringing it into contact with a contoured metal surface. After the material is in place, heat and pressure are supplied by a hydraulic press, the time and temperature varying with the nature of the material. For rubber products, vulcanization occurs simultaneously. Most plastic molding is now done by the injection method, which is more economically efficient.

See injection molding.

Compton effect. One of the principal processes by which high-energy electromagnetic radiation (γ -rays) interacts with or is absorbed by matter. In the Compton process the γ -ray frees an electron in matter as if the electron were unbound, dividing the momentum of the γ -ray between the ejected electron and a new γ -ray of lower energy going off in a new direction.

computational chemistry. Use of computers in organic synthesis and in chemical engineering as

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